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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/898,726      | 07/03/2001  | Russell A. Houser    | 509192000220        | 4439             |

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EXAMINER

FARAH, AHMED M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3739

DATE MAILED: 09/25/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/898,726

Applicant(s)  
Houser et al.

Examiner  
A. Farah

Art Unit  
3739



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: the Brief Description of the Drawings fails to provide description for Figs. 33 (A,B); Figs. 34 (A,B); Figs. 35 (A,B); and Figs. 36 (A,B). Although the Detailed Description section of the specification describes these Figures, it is required that the Applicants present a brief description (Figures caption) for all drawings in the application under the specification section marked as the Brief Description of the Drawings. Correction is required. ✓ o/c

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 7-12, 15, 18, 22, 24, 25, 28-36, 38, 40, 41, 47-49, 51, 52, 55-60, 63-68, 75-82, 84, 91, and 94-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen U.S. Pat. No. 5,336,252.

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As to claims 1-5, 47-49, and 76-78, Cohen discloses a device and methods for modifying the flow through the cardiac valve, the device comprising a guide catheter for delivering a cinching member having a central region **148** and at least two opposing anchoring regions **150** to the cardiac tissue **109**. In regard to claims 76-78, the electrode **142** (lead wire) of Cohen would induce thermal shrinkage of collagen in the tissue, thereby modifying flow through the heart valves. See Figures 20-22; Col. 4, line 66- Col. 5, line 26; and Col.14, lines 37-41.

As to claims 7, 8, 18, 22, 38, 51, 52, 84, he teaches that the electrode **142**, and therefore the anchoring regions **150**, are substantially coated with a biocompatible insulator **144**, such as polyurethane or silicone (Col. 14, lines 35-37). In reference to claims 22 and 38, the coating material of Cohen, which is selected from the group consisting of polyurethane or silicone, is treated to be radiopaque to certain forms of radiation.

As to claims 9-11, 28-33, 56, 58, 59, and 94-97, he discloses fixation/anchoring means selected from the group consisting crimping or adhesive bonding (Col. 14, lines 41-45); V-shapes (Fig. 22); and jaws, hooks, or pivoting locks (Figs. 3 and 18). In regard to claim 29, the anchoring regions are configured to pierce the tissue.

As to claims 24, 60, 63 and 91, Fig. 22 of Cohen clearly shows that the central region of the cinching device **140** defines a first plane and the anchoring regions **150** define a second plane, the second plane defining an angle relative to the first plane.

As to claims 34-36 and 66-68, he further discloses a stylet **108** (guide wire) with a hooked distal tip **110** disposed at the distal end of the device, the stylet being slightly disposed

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in the catheter lumen and being manipulated from its proximal end. See Fig.18; Col. 13, lines 16-28; and claim 1 of Cohen. In reference to claims 80-82, his device would provide the methods as presently claimed.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 37 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Muller U.S. Pat. No. 5,725,521.

Although Cohen, described above, uses sliding mechanism to advance and retract the stylet (guide wire), he does not particularly teach its type. Muller teaches an alternative heart modifying device and methods comprising a thumb-slide advancing mechanism. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the device of Cohen with Muller and use a thumb-slide as an alternative advancing mechanism.

rejects Cohen's invention under 103(a) as being unpatentable over:

6. Claims ~~6~~, 13, 14, 26, 27, 50, 61, ~~62~~, 83, 85-88, 92, and ~~93~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Jeevanandam et al. U.S. Pat. No. 5,957,916.

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Cohen, described above, do not teach a plurality of cinching/anchoring member wherein the separation angles between the anchoring members relative a central plane is about  $60^{\circ}$  to  $120^{\circ}$  as presently claimed. Jeevanandam et al. disclose a myocardial revascularization device and method for modifying flow through the heart, the device comprising a plurality of anchoring members 44. The separation angles between their anchoring members relative to a common central plane falls within a range of about  $60^{\circ}$  to  $120^{\circ}$  as presently claimed. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Cohen in view of Jeevanandam et al. and use plurality of separated anchoring members in order to substantially secure the treatment device near the tissue being treated.

7. Claims 19-21, 23, 39, 43-46, and 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Crowley et al. U.S. Pat. No. 6,004,264.

Cohen, described above, does not teach the use of therapeutic coating, radiopaque material selected from the group consisting of platinum, gold, *etc.*, or an ultrasound sensor connected to a monitor for guiding the system as presently claimed.

However, Crowley et al. disclose an ultrasound guided catheter and method for modifying the flow through a cardiac valve, the device comprising: therapeutic agents; radiopaque markers; coating material selected from the group consisting of platinum and gold; and an ultrasound sensor disposed at the tip of the catheter device for monitoring the treatment and operations of the device. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Cohen with Crowley et al. to employ radiopaque markers and

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ultrasound sensors in order to monitor the operation of the system. It would have been further obvious to one skilled in the art at the time of the applicant's invention to use gold or platinum as an alternative coating material.

8. Claims 16, 17, 42, 53, 54, 89, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Abrams U.S. Pat. No. 5,492,119.

Although the hooked member **108** of Cohen conforms to a predetermined shape, he does not particularly teach his hooked member is made from a shape memory material. He further fails to describe the material in which it is made of.

Abrams teaches an alternative medical catheter device comprising a biocompatible material selected from the group consisting of shape memory alloys, such as Nickel-Titanium alloy, for modify the flow through a heart valve. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Cohen in view of Abrams to use a cinching/anchoring member made from a shape memory material so as to have a cinching/anchoring member that conforms to a predetermined shape after it is deployed through the catheter.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

1. Shturman

U.S. Pat. No. 5,443,446

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2. Ellis et al.

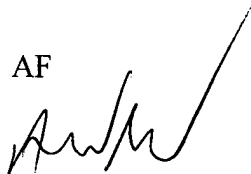
U.S. Pat. No. 6,056,743

3. Oz et al.

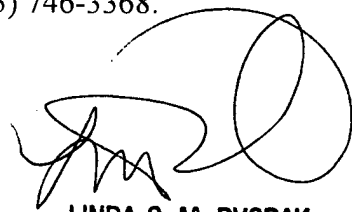
U.S. Pat. No. 6,269,819

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for the Examiner is (703) 746-3368.

AF



09/30/02



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